PMS Procedure

Evita XL

Notes on field of application: Tests marked with the "check" symbol are listed in the Inspection Report. The test results are to be documented in the Inspection Report. This Test Certificate applies to software version 5.n.

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1 Unit configuration

1.1 General

The basic unit configuration covers the following components:
EvitaXL
Trolley
Ventilation tubing system
Expiratory valve
Temperature sensor (option)
CO2 sensor (option)

1.2 Serial number (SN)

☑ **1.2.1 EvitaXL** **[_____txt]**

Serial number (SN) of EvitaXL (Note: The serial number is located on the rating plate.

☑ **1.2.2 Expiratory valve 1** **[_____txt]**

Serial number (SN) of expiratory valve 1

☑ **1.2.3 Expiratory valve 2** **[_____txt]**

Serial number (SN) of expiratory valve 2

☑ **1.2.4 Expiratory valve 3** **[_____txt]**

Serial number (SN) of expiratory valve 3

☑ **1.2.5 CO2 sensor (option)** **[_____txt]**

Serial number (SN) of CO2 sensor

☑ **1.2.6 Control panel** **[_____txt]**

Serial number (SN) of control panel

1.3 Software version

☑ **1.3.1 Unit software version** **[_____txt]**

Plug the power plug of the device into the socket-outlet.

Switch on the device.
The unit completes its self-test.

Set unit to operating mode.

Press "System Setup" button. The "System Setup" window is shown on the display.

Press "Service" softkey.

Read and note down the software version from the display.

1.4 Operating hours

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☑ **1.4.1** **Unit operating hours** **[_____h]**

Plug the power plug of the device into the socket-outlet.

Switch on the device.
The unit completes its self-test.

Set unit to operating mode.

Press "System Setup" button. The "System Setup" window is shown on the display.

Press "Service" softkey.

Read and note down the operating hours from the display.

☑ **1.5** **DC module (Evita 4 with XL option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: The DC module is identifiable by the cable connections for the external battery)

☑ **1.6** **Evita Link (option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: On the Communication PCB the "2xRS232", "2xCAN" and "1x analog output" sockets are fitted.)

☑ **1.7** **NeoFlow (option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: On the PCB the "NeoFlow sensor" socket is fitted.)

☑ **1.8** **PPS (option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: During operation, press the "Ventilator Settings" button and the "More" softkey. If the "PPS" softkey is installed, the option is available.

☑ **1.9** **ATC (Evita 4 with "XL" option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: During operation, press the "Ventilator Settings" button, the "BIPAP" softkey and the "Additional Setting" softkey. If the "ATC" softkey is installed, the option is available.

☑ **1.10** **IFCO Carrier PCB (option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: On the PCB the "Nurse Call" socket is fitted.)

☑ **1.11** **Mask ventilation (option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: During operation, press the "Start/Standby" button and the "Tube/Mask" softkey. If the "Mask (NIV)" softkey is installed, the option is available.

☑ **1.12** **Capno Plus (option)** **[_____OK]**

Indicate by a tick in the Inspection Report if the option is installed. (Note: On the CO2 Carrier PCB the socket for the CO2 connection is fitted.)

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2 Maintenance parts

2.1 General

Fitting of maintenance parts is classified as repair and is therefore not included in the inspection price. Special agreements with the customer shall be taken into consideration. Performance of the maintenance work involved is described in the service documentation.

2.2 Maintenance intervals

☑ **2.2.1 12-month set 4114761** [_____]

The 12-month set 4114761 is applicable only to the USA. Enter date of next change in Inspection Report field. This date must be transferred to a new Inspection Report of the unit.

☑ **2.2.2 1-year maintenance interval** [_____dat]

Enter date of next change in Inspection Report field. This date must be transferred to a new Inspection Report of the unit.

☑ **2.2.2.1 Diaphragm** [_____]

Number: 1
Order no.: 8410181
Maintenance interval in months: 12

Replace diaphragm in expiratory valve.

☑ **2.2.2.2 Sealing washer** [_____]

Number: 1
Order no.: 8407979
Maintenance interval in months: 12

Replace sealing washer in expiratory valve.

☑ **2.2.3 24-month set 4114762** [_____]

The 12-month set 4114762 is applicable only to the USA. Enter date of next change in Inspection Report field. This date must be transferred to a new Inspection Report of the unit.

☑ **2.2.4 2-year maintenance interval** [_____dat]

INFO:
At the 2-yearly maintenance the spare parts listed under step 2.2.2 must additionally be replaced.

Enter date of next change in Inspection Report field. This date must be transferred to a new Inspection Report of the unit.

☑ **2.2.4.1 Lithium battery** [_____]

Number: 1
Order no.: 1835343
Maintenance interval in months: 24

Replace lithium battery on CPU 68332 PCB.

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☑ **2.2.4.2** **External rechargeable battery (option)** [_____]

Number: 2
Order no.: 1843303
Maintenance interval in months: 24

Replace external rechargeable battery in trolley.

☑ **2.2.4.3** **Filter** [_____]

Number: 2
Order no.: 8408208
Maintenance interval in months: 24

Replace filter in Dräger gas connection block.

☑ **2.2.4.4** **Filter** [_____]

Number: 2
Order no.: 8408208
Maintenance interval in months: 24

Replace filter in FAS gas connection block.

☑ **2.2.4.5** **Flat seal** [_____]

Number: 1
Order no.: 8408204
Maintenance interval in months: 24

Replace flat seal in Dräger gas connection block.

☑ **2.2.4.6** **O-ring** [_____]

Number: 2
Order no.: 8411516
Maintenance interval in months: 24

Replace O-ring in FAS gas connection block.

☑ **2.2.4.7** **Rechargeable battery** [_____]

Number: 2
Order no.: 1845284
Maintenance interval in months: 24

Replace rechargeable battery in DC module (power supply unit).

☑ **2.2.5** **6-year maintenance interval** [_____**dat**]

INFO:
When performing the 6-year maintenance, replace also the spare parts listed under test steps 2.2.2 and 2.2.4.

Enter date of next change in Inspection Report field. This date must be transferred to a new Inspection Report of the unit.

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☑ **2.2.5.1** **Diaphragm** [_____]

Number: 2
Order no.: 8411513
Maintenance interval in months: 72

Replace diaphragm in FAS gas connection block.

☑ **2.2.5.2** **Valve tappet** [_____]

Number: 2
Order no.: 8411514
Maintenance interval in months: 72

Replace valve tappet in FAS gas connection block.

☑ **2.2.5.3** **Pressure regulator** [_____]

Number: 2
Order no.: 8408205
Maintenance interval in months: 72

Replace pressure reducer on Dräger gas connection block.

☑ **2.2.5.4** **Real-time clock** [_____]

Number: 1
Order no.: 1837087
Maintenance interval in months: 72

Replace real-time clock on CPU 68332 PCB.

2.3 Cleaning intervals

INFO:
Careful vacuum the pneumatics with a vacuum cleaner at each inspection or maintenance.

☑ **2.3.1** **Pneumatics** [_____OK]

Remove the two screws (front and rear left) and raise the electronics unit.
Carefully clean out the pneumatics unit with a vacuum cleaner.
Lower the electronics unit and affix it to the pneumatics unit by the two screws.

2.4 Calibration intervals

☑ **2.4.1** **PEEP/PIP valve** [_____OK]

INFO:
Calibrate the PEEP/PIP valve on every inspection! The PEEP/PIP valve calibration procedure is described in the Repair Instructions.

Calibration of the PEEP/PIP valve was successful (Note: The PEEP/PIP valve calibration procedure is described in the Repair Instructions.

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3 Electrical safety

☑ **3.1 Visual check** **[_____OK]**

3.1.1 Power cable

The unit's power cable is undamaged.
[OK]

3.1.2 Screw-type terminal of power cable

The screw-type terminal of the power cable is undamaged.
[OK]

3.1.3 Power switch

The power switch with mechanical interlock is undamaged. The protective cap of the power switch drops down over the switch after it is switched on.
[OK]

3.1.4 CO2 sensor (option)

The CO2 sensor, the housing and the connecting cable are undamaged.
[OK]

3.1.5 Fuse links

The fitted fuse links match the ratings indicated on the power supply unit.
[OK]

3.2 General note

WARNING:
If the unit is connected to a network, it must be disconnected from the network before testing its electrical safety. Otherwise other devices that are connected to the network could be damaged.

The following section details the additional tests of electrical safety to VDE 0751 and IEC 60601-1/UL 2601. Which standard is applied depends on the relevant national regulations.
If necessary, make the following settings for the unit on the measuring devices: Protection class ”SK 1”, safety class ”BF”.

3.2.1 Internal rechargeable battery (if installed)

Unplug connector of external battery (option) from power supply unit.

Switch on the device.

Set controlled ventilation.

Unplug the power plug of the device from the socket-outlet.
The unit continues ventilating without interruption.

Operate the unit with the internal rechargeable battery until the battery capacity is used up (Note: The capacity of the internal rechargeable battery is enough to power the unit for 10 minutes).
[OK]

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☑ **3.2.2** **Mains failure alarm and data saving** **[_____OK]**

INFO:
The unit must operate without mains power supply until the internal battery (if fitted) is discharged. Only then is the power failure alarm given!

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Set the unit to "controlled ventilation" mode.

Interrupt the mains power supply.
The audible power failure alarm sounds.

Restore the mains power supply.
Following a short self-test, the unit must restart in the ventilation mode selected in step 1.

3.3 Electrical safety according to VDE 0751

Preconditions for testing of electrical safety:

If the "external battery" option is installed, unplug the red connection ("external battery" option) from the power supply unit (Note: The red connector is plugged into the rear of the power supply unit).

Discharge the internal battery (DC module) by unplugging the unit's mains power cable and leaving the unit running for about 10 minutes.

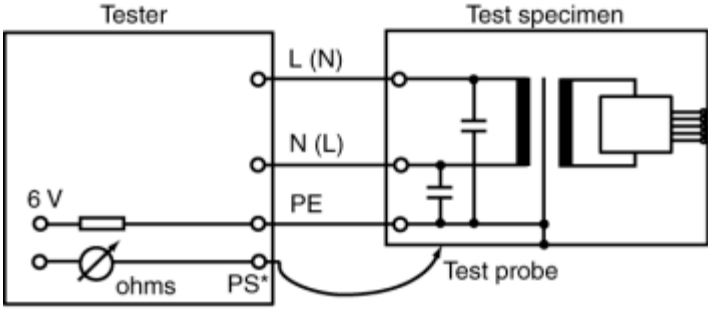
☑ **3.3.1** **Protective earth conductor resistance** **[_____Ohm]**

WARNING:
Test the PE resistance with the power cable connected!

A test alternating voltage of approx. 6 V is connected via a current limiter to the protective conductor of the test specimen. The test probe scans the conductive parts of the test specimen. The PE resistance is derived from the flowing current and the voltage connected to the test specimen. The PE current is min. 10 A.

Connect the test probe to the following test points one after the other:
Power supply unit earthing studs
Pneumatics (gas connection and metal connectors)
Inspiratory block
Front panel (screws)
Rails (on side of unit)

The protective earth conductor resistance must not exceed 0.3 ohms in each case.



*PS = Test probe

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3.3.2 Equivalent device leakage current

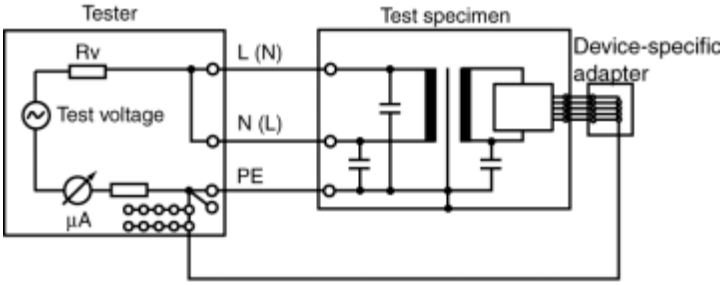
INFO:
The precondition for the test is that the unit has been operated with no mains voltage and no external rechargeable battery until the internal battery is flat and the acoustic power failure warning sounds!

Do not establish the test set-up until the audible power failure alarm sounds continuously (Note: The display must be blank.).

A test voltage in the amount of the mains voltage is connected between the shorted mains connection, the measuring device (tester) and the protective conductor of the test specimen. The current flowing from the live components via the insulation, the capacitors and the shorted user ports to the protective conductor is the equivalent device leakage current.

The contacts of the ILV interface are shorted and earthed. To achieve this make the following connection:

Connect ILV connection and ground stud with cable 7910393. (Note: As an alternative, the socket of the temperature module and the earthing stud can be interconnected with cable 7910364.)
The value of the re-measurement may exceed the initial measured value by max. 50%, but must not exceed 1000 µA.



☑ **3.3.2.1 Initial measured value** **[_____µA]**

INFO:
Each initial measured value should be included in a new Inspection Report.

The initial measured value must not exceed 1000 µA.

☑ **3.3.2.2 Repeat measurement** **[_____µA]**

The value of the re-measurement may exceed the initial measured value by max. 50%, but must not exceed 1000 µA.

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3.3.3 Equivalent patient leakage current

INFO:
Do not switch off the unit. The precondition for the test is that the unit has been operated with no mains voltage and no external rechargeable battery until the internal rechargeable battery is flat and the acoustic power failure warning sounds!

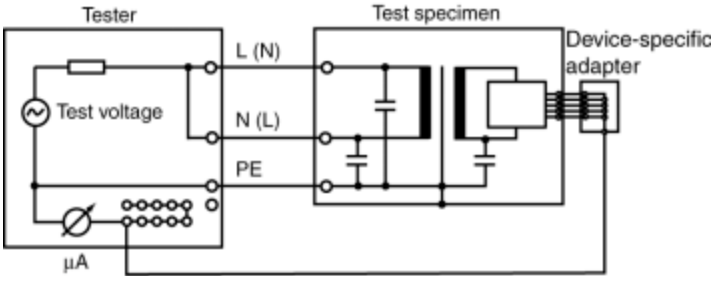
Do not establish the test set-up until the audible power failure alarm sounds continuously (Note: The display must be blank.).

A test voltage in the amount of the mains voltage is connected between the shorted mains connection, the measuring device (tester) and the shorted sensor cables of the test specimen. The current flowing from the live components via the insulation, the capacitors and the shorted user ports is the equivalent patient leakage current.

The measurement is taken between the shorted sensor contacts and the earthing stud of the power supply unit with the power plug contacts shorted and earthed.

To achieve this make the following connections:
Create connections between the tester and the test specimen for the "equivalent patient leakage current test".
Interconnect ILV port and tester with cable 7910393.
Alternatively: Interconnect socket of temperature module and tester with cable 7910364.

The value of the re-measurement may exceed the initial measured value by max. 50%, but must not exceed 5000 µA.



☑ **3.3.3.1 Initial measured value** **[_____µA]**

INFO:
Each initial measured value should be included in a new Inspection Report.

The initial measured value must not exceed 5000 µA.

☑ **3.3.3.2 Repeat measurement** **[_____µA]**

The value of the re-measurement may exceed the initial measured value by max. 50%, but must not exceed 5000 µA.

3.3.4 Trolley multiple socket strip (option)

☑ **3.3.4.1 Fuse links** **[_____OK]**

The fuse links match the ratings on the rating plate.

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☑ **3.3.4.2** **Protective earth conductor resistance** **[_____Ohm]**

The protective earth conductor resistance of the socket outlets must not exceed 0.3 ohms in each case.

3.3.4.3 **Equivalent device leakage current**

INFO:
The test is carried out without the EvitaXL (Evita 4 with "XL" option) or other units.

The value of the re-measurement may exceed the initial measured value by max. 50%, but must not exceed 100 µA.

☑ **3.3.4.4** **Initial measured value** **[_____µA]**

INFO:
Each initial measured value should be included in a new Inspection Report.

The initial measured value must not exceed 100 µA.

☑ **3.3.4.5** **Repeat measurement** **[_____µA]**

The value of the re-measurement may exceed the initial measured value by max. 50%, but must not exceed 100 µA.

3.4 **Electrical safety to IEC 60601-1/UL 2601**

Preconditions for testing of electrical safety:

If the "external battery" option is installed, unplug the red connection ("external battery" option) from the power supply unit (Note: The red connector is plugged into the rear of the power supply unit).

Discharge the internal battery (DC module) by unplugging the unit's mains power cable and leaving the unit running for about 10 minutes.

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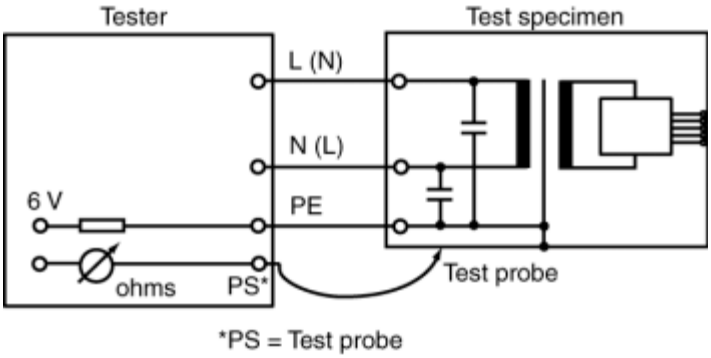
☑ **3.4.1** **Protective earth conductor resistance** **[_____Ohm]**

WARNING:
Test the PE resistance with the power cable connected!

A test alternating voltage of approx. 6 V is connected via a current limiter to the protective conductor of the test specimen. The test probe scans the conductive parts of the test specimen. The PE resistance is derived from the flowing current and the voltage connected to the test specimen. The PE current is min. 10 A.

Connect the test probe to the following test points one after the other:
Power supply unit earthing studs
Pneumatics (gas connection and metal connectors)
Inspiratory block
Front panel (screws)
Rails (on side of unit)

The protective earth conductor resistance must not exceed 0.3 ohms in each case.

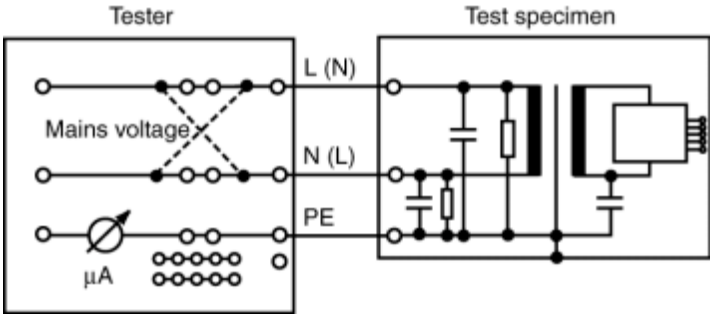


3.4.2 **Earth leakage current**

Mains voltage is applied to the mains connection of the test specimen as a test voltage. The test specimen is in operational condition. The current flowing from the live components via the insulation and the capacitors to the protective earth conductor is the earth leakage current.

In response to the first fault condition (S.F.C. = Single Fault Condition) the neutral conductor circuit is opened.

Switch the power switch to "ON".



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☑ **3.4.2.1** **Normal condition N.C. (IEC)** **[_____µA]**

The earth leakage current must not exceed 500 µA.

☑ **3.4.2.2** **Normal condition N.C. (UL)** **[_____µA]**

The earth leakage current must not exceed 1000 µA.

☑ **3.4.2.3** **Single fault condition S.F.C. (IEC)** **[_____µA]**

Open circuit in neutral conductor.

The earth leakage current must not exceed 500 µA.

Subsequently the earth leakage current test is repeated with the power plug rotated. (Note: This condition can be established internally on some testers.)

☑ **3.4.2.4** **Single fault condition S.F.C. (UL)** **[_____µA]**

Open circuit in neutral conductor.

The earth leakage current must not exceed 1000 µA.

Subsequently the earth leakage current test is repeated with the power plug rotated. (Note: This condition can be established internally on some testers.)

☑ **3.4.2.5** **Normal condition N.C. (IEC)** **[_____µA]**

The earth leakage current must not exceed 500 µA.

☑ **3.4.2.6** **Normal condition N.C. (UL)** **[_____µA]**

The earth leakage current must not exceed 1000 µA.

☑ **3.4.2.7** **Normal condition N.C. (IEC)** **[_____µA]**

Open circuit in neutral conductor.
The earth leakage current must not exceed 500 µA.

☑ **3.4.2.8** **Single fault condition S.F.C. (UL)** **[_____µA]**

Open circuit in neutral conductor.
The earth leakage current must not exceed 1000 µA.

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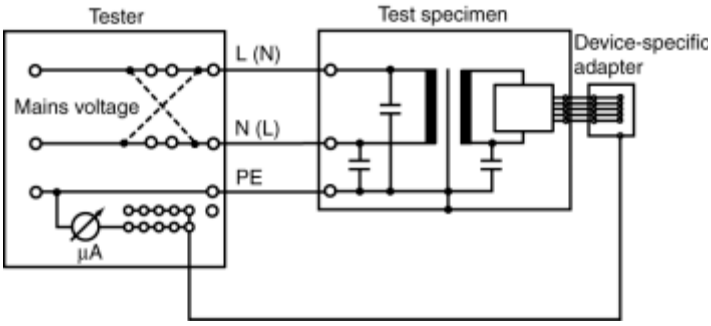
3.4.3 Patient leakage current, ILV port

Mains voltage is applied to the mains connection of the tester as a test voltage. The current flowing from the shorted user ports to the protective conductor is the patient leakage current.

In response to the first fault condition (S.F.C. = Single Fault Condition) the neutral conductor circuit is opened.

Interconnect ILV port and tester with cable 7910393.

Switch the power switch to "ON".



☑ **3.4.3.1 Normal condition N.C.** **[_____µA]**

The patient leakage current must not exceed 100 µA.

☑ **3.4.3.2 Single fault condition S.F.C.** **[_____µA]**

Open circuit in neutral conductor.

The patient leakage current must not exceed 500 µA.

Subsequently the patient leakage current test is repeated with the power plug rotated. This condition can be established internally on some testers.

☑ **3.4.3.3 Normal condition N.C.** **[_____µA]**

The patient leakage current must not exceed 100 µA.

☑ **3.4.3.4 Single fault condition S.F.C.** **[_____µA]**

Open circuit in power cable conductor.
The patient leakage current must not exceed 500 µA.

3.4.4 Trolley multiple socket strip (option)

☑ **3.4.4.1 Fuse links** **[_____OK]**

The fuse links match the ratings on the rating plate.

☑ **3.4.4.2 Protective earth conductor resistance** **[_____Ohm]**

The protective earth conductor resistance of the socket outlets must not exceed 0.3 ohms in each case.

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☑ **3.4.4.3** **Earth leakage current (N.C.)** **[_____µA]**

The earth leakage current must not exceed 50 µA.

☑ **3.4.4.4** **Single fault condition (S.F.C.)** **[_____µA]**

Open circuit in neutral conductor.
The earth leakage current must not exceed 100 µA.

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4 Function and condition test

☑ **4.1 Accompanying documents** [_____OK]

4.1.1 Instructions for Use

Instructions for Use are available according to user (Note: Comply with national laws and standards!).
[OK]

4.1.2 Instructions for Use of options

Instructions for Use of options are available according to the user (Note: Comply with national laws and standards!).
[OK]

4.1.3 Medical Products Logbook (applicable to Germany only)

The Medical Products Logbook is available according to the user (Note: Comply with national laws and standards!).
[OK]

☑ **4.2 Visual check** [_____OK]

Check condition of unit and essential accessories.

4.2.1 Housing

The housing is not damaged or dirty. The housing shows no corrosion damage. Also repair any paintwork damage.
[OK]

4.2.2 Operating and display elements

The operating and display elements are not damaged or dirty.
[OK]

4.2.3 Labelling

The labelling, including on adhesive option labels, is complete and legible
[OK]

4.2.4 AIR and O2 compressed gas ports

The AIR and O2 compressed gas ports are undamaged.
[OK]

4.2.5 PCBs

The PCBs are all affixed by two screws to the unit.
[OK]

4.2.6 Sockets (sensor, communication)

The connectors on the PCBs are undamaged.
[OK]

4.2.7 Power pack

The power supply unit is not damaged or dirty.
[OK]

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4.2.8 DC connection for external battery (option)

The DC connection is undamaged.
[OK]

4.2.9 Remote socket (optional)

INFO:
If a remote socket is installed on the Evita 4 with the "XL" option, it must be closed off by a cap. There must also be a warning label affixed next to the remote socket.

The remote socket is closed off by a cap. The cap is undamaged.

The warning notice is legible, and not dirty or damaged.
[OK]

4.2.10 Cooling air fan

The cooling air fan is not damaged or dirty. The cooling air fan rotates smoothly. Clean out the cooling air fan with a vacuum cleaner if it is dirty.
[OK]

4.2.11 Cooling air filter

The cooling air filter is not damaged, dirty or squashed. Replace the cooling air filter as necessary.
[OK]

Remove the front panel (control panel) to perform the following steps.

4.2.12 Cover

The cover to the right of the inspiratory block is undamaged.
[OK]

Remove the screw from the cover and lay the cover aside.

4.2.12.1 Room air filter

The room air filter F3.1 in the cover is not damaged, dirty or squashed. Replace the room air filter as necessary.
[OK]

4.2.12.2 Fan

The fan behind the cover is not damaged or dirty. The fan rotates smoothly and is not dirt clogged. Vacuum the fan to clean it as necessary
[OK]

4.2.12.3 O2 amplifier with non-return valve

Unscrew O2 amplifier with non-return valve.
The O2 amplifier with non-return valve D3.1 is not damaged or dirty.
[OK]

4.2.12.4 O2 sensor capsule

Check expiry date of O2 sensor capsule. Replace the O2 sensor capsule as necessary.
[OK]

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4.2.12.5 Lip seal (O2 sensor mount)

The lip seal of the O2 sensor mount in the inspiratory block is undamaged. Replace the lip seal as necessary.
[OK]

4.2.12.6 Seal

The seal between the inspiratory block and the O2 amplifier is undamaged. Replace the seal as necessary.
[OK]

Insert O2 sensor capsule into inspiratory block.

Fit O2 amplifier with non-return valve on unit.

4.2.12.7 Inspiratory socket

The inspiratory socket is not dirty or damaged.
[OK]

4.2.12.8 Nebuliser port

The nebuliser port is identified by a nebuliser icon. The nebuliser port is not dirty or damaged.
[OK]

Fit cover on unit.

4.2.13 Expiratory block

4.2.13.1 flow sensor

The flow sensor is undamaged.
[OK]

4.2.13.2 Flow sensor mount

The flow sensor mount is not dirty or damaged.
[OK]

4.2.13.3 Joint seal

The joint seal between the flow sensor and the expiratory valve is undamaged and the connector seal is correctly seated.
[OK]

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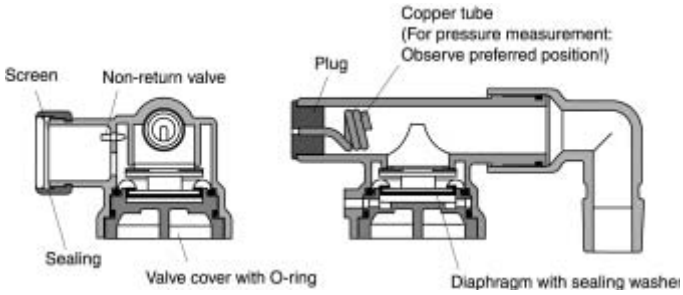
4.2.13.4 Expiratory valve without water trap

WARNING:
When fitting, keep to the preferential direction of the plug with copper pipe!

Visual check of individual components - see Fig.. The individual components of the expiratory valve are undamaged.
[OK]

Assemble the expiratory valve(s) in functional condition.

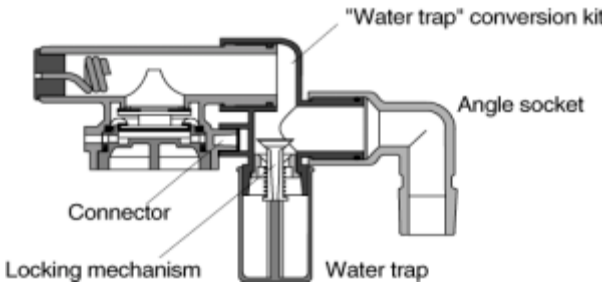


4.2.13.5 Expiratory valve with water trap

WARNING:
When fitting, keep to the preferential direction of the plug with copper pipe!

Visual check of individual components as described in test item 4.2.14.4 plus additional visual check of individual components – see Fig.
The individual components of the expiratory valve and the water trap are undamaged.
[OK]

Assemble the expiratory valve(s) in functional condition.



4.2.13.6 Expiratory valve mount

The expiratory valve mount is not damaged or dirty. The expiratory valve locks safely into the mount.
[OK]

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4.2.13.7 Patient system heater ventilation grille

The patient system heater ventilation grille is not dirty. Clean the ventilation grille, or suction it clean with a vacuum cleaner, as necessary (Note: The ventilation grille is fitted on the right under the expiratory valve).
[OK]

4.2.13.8 Lip seals

The lip seals between the expiratory valve and the unit are undamaged. Replace lip seals if necessary.
[OK]

4.2.14 Control panel with attachment

4.2.14.1 Housing and touchscreen

The housing and touchscreen are not dirty or damaged.
[OK]

4.2.14.2 Keypad, control knob and labelling

The keypad and the control knob are undamaged. The labelling is complete and legible.
[OK]

4.2.14.3 Swivel function with interlock and removability

The control panel can be swivelled and locked in place. The control panel can be removed without problem.
[OK]

4.2.14.4 Rail mounting with interlock

The rail mounting with interlock is undamaged.
[OK]

4.2.14.5 Cable winder

The cable winder is undamaged.
[OK]

4.2.14.6 Connecting cable

The control panel connecting cable is undamaged. The connecting cable is secured to the control panel and to the front with 2 screws each.
[OK]

4.2.14.7 Mounting

The interlock for mounting of the control panel is undamaged.
[OK]

4.2.14.8 Lid of base unit

The lid of the base unit is undamaged. If no tray or Dräger monitor is fitted to the unit, the four openings in the lid must be closed off with sealing plugs.
[OK]

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4.2.14.9 Tray

The tray is undamaged.
[OK]

4.2.15 CO2 sensor (option)

4.2.15.1 Sensor housing with anti-kink sleeve

The housing with anti-kink sleeve is undamaged. The housing is bonded tight.
[OK]

4.2.15.2 Cable with plug

The cable with plug is undamaged. The cable insulation is undamaged.
[OK]

4.2.15.3 Window in CO2 sensor

The window in the CO2 sensor is clean and undamaged.
[OK]

4.2.15.4 Test filter

The mounting and the connecting cable of the test filter are undamaged.
The test filter is clean and not scratched.
[OK]

4.2.15.5 Cuvettes

The windows of the cuvettes are bonded in flat, clean and undamaged.
[OK]

4.2.15.6 Park bracket for CO2 sensor

The windows in the park bracket are clean and undamaged.
[OK]

4.2.16 Two-column trolley (Evita 4 with "XL" option)

INFO:
Observe the repair information concerning the ”Trolley”.

4.2.16.1 Castor screw fitting

Check the tightening torque of the castors every six months!

Check the castor screws are firmly seated in their fittings:

Black castors 35 Nm (25.9 lb-ft)
Chrome-plated castors 33 Nm (24.4 lb-ft)
[OK]

If the castor is not tightened to a torque of 35 Nm/33 Nm (i.e. the castor pin turns before 35 Nm/33 Nm is reached), replace the castor and the spring ring or strain washer as appropriate.

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4.2.16.2 Screw fitting of yellow cap

Check the screw fitting of the yellow cap every six months!

Check the screws of the yellow cap are firmly seated in their fittings.
[OK]

4.2.16.3 Screw fitting of unit mount

Check the screw fitting of the unit mount every six months!

Check the screws of the unit mount (6 mm hexagon socket screws) are firmly seated in their fittings.
[OK]

4.2.16.4 Accessories

Humidifier bracket
The humidifier bracket is undamaged.

Cabinet
The cabinet is undamaged.

Multiple socket strip
The multiple socket strip is undamaged.

O2 distributor
The O2 distributor is undamaged.

”Battery in cabinet” conversion kit with connecting cable (option)
The ”Battery in cabinet” conversion kit with connecting cable shows no signs of damage.
[OK]

4.2.17 Single-column trolley

☑ **4.2.17.1 Castor screw fitting** **[_____OK]**

INFO:
Check the tightening torque of the castors every six months!

Check the castor screws are firmly seated in their fittings: The tightening torque is 25 Nm (18.5 lb-ft).

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4.2.17.2 Accessories

Respiratory gas humidifier bracket (option)
The respiratory gas humidifier bracket is undamaged.

Cylinder bracket (option)
The cylinder bracket is undamaged.

Multiple socket outlet (option)
The multiple socket outlet is undamaged.

External rechargeable batteries (option)
The external rechargeable batteries in the pedestal of the trolley are undamaged.

Connecting cable of external battery (option)
The connecting cable of the external battery is undamaged.
[OK]

4.2.18 Wall rail bracket (option)

The wall rail bracket is undamaged.
[OK]

4.2.19 Hinged arm (option)

The hinged arm is moving smoothly and is undamaged.
[OK]

4.2.20 Temperature sensor (option)

The temperature sensor is undamaged.
[OK]

4.2.21 Compressed gas connecting hoses

INFO:
Comply with national laws and standards for compressed gas connecting hoses!

The compressed gas connecting hoses are undamaged. There are no leaks in the compressed gas connecting hoses.
[OK]

4.2.22 Tubing systems as per Instructions for Use

The tubing systems as per the Instructions for Use are undamaged.
[OK]

4.2.23 Dräger test lung (adults)

The adult test lung comprises the mask tube, ISO size 7 catheter connection socket and 2 L breathing bag. The mask tube, the ISO size 7 catheter connection socket and the 2 L breathing bag are complete and undamaged. (Note: The breathing bag must not be over-inflated or torn.)
[OK]

4.2.24 SIEMENS test lung (adults)

The SIEMENS test lung is not cracked or porous and is undamaged.
[OK]

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4.2.25 Bellows K (neonatal)

The bellows K are undamaged.
[OK]

4.2.26 Accessories for neonatal flow (option)

Flow sensor cable
The flow sensor cable is undamaged. The socket on the flow sensor cable locks safely into the flow sensor insert.

Flow sensor ISO 15
The ISO 15 flow sensor and the flow sensor insert are undamaged.

Water trap for expiratory valve (option)
The water trap for the expiratory valve is undamaged. The water trap for the expiratory valve must be used with the optional ”neonate flow” feature
[OK]

4.2.27 Drug nebuliser (white housing)

WARNING:
If other pneumatic drug nebulisers are used, significant variances in the breathing volume and the inspiratory oxygen concentration may result!

INFO:
Do not connect the drug nebulizer with the "black" housing to the unit!

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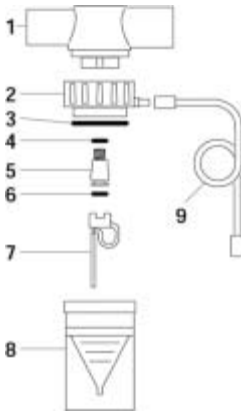
4.2.27.1 Components of the drug nebulizer

Check the following components for damage and dirt contamination:

1 = Patient connection
2 = Drug nebulizer housing, white
3 = Flat seal
4 = O-ring
5 = Nozzle
6 = O-ring
7 = Atomizer
8 = Container
9 = Drug nebulizer tube

The listed drug nebulizer components are not damaged or dirty.
[OK]



4.2.27.2 Drug nebulizer function test

Fill drug nebulizer with water up to the "3" mark.

Supply drug nebulizer with 1.8 bar to 2.2 bar.

A mist is produced at the outlet of the drug nebulizer.
[OK]

4.2.28 Special accessories (option)

The special accessories listed below are undamaged:

Resutator 2000
Child Resutator 2000
Baby resuscitator

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☑ **4.3** **Non-return valve in expiratory valve** **[_____OK]**

INFO:
Test all expiratory valves listed on the Inspection Report/Log.

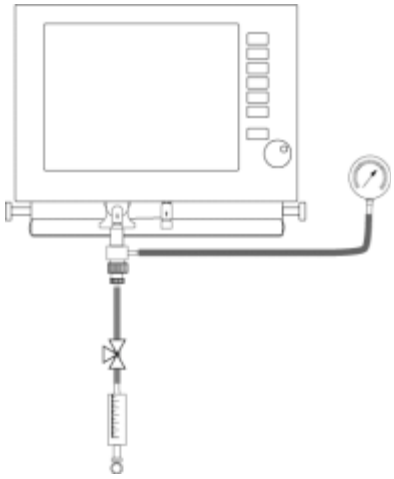
Precondition: The unit is off and the expiratory valves are functional.

Connect the non-return valve in the expiratory valve to the switched-off unit.

Connect the test set-up below to the expiratory socket.

Use the syringe to generate a negative pressure of -7 mbar and then reduce it to -4 mbar.

After approx. 5 seconds, the vacuum for each expiratory valve tested is still at least -1mbar.



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☑ **4.4** **Power-on test and unit check at Standby** **[_____OK]**

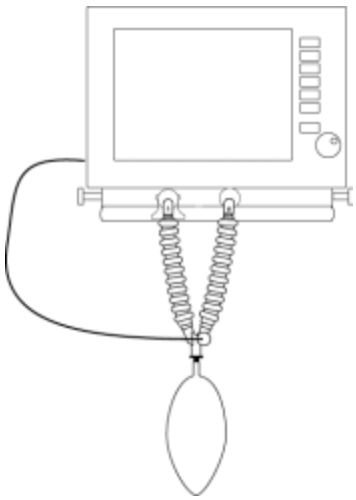
INFO:
In the following tests, the IPPV and BIPAP ventilation modes are used in adult and pediatric mode. If one of those modes has not been programmed and is not intended to be applied by the user, it can be set up for the test as follows: Press the "System Setup" button, then the "Therapy" softkey and the "Patient range" softkey, enter code 3032, using the control knob select the "Adult" or "Pediatric" menu and then push in the knob. Re-enter the detected setting following the inspection prior to handover of the unit.

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Assemble the unit ready for use.

Connect adult tubing system without humidifier.

Connect the following sensors to the EvitaXL, if available:
AWT temperature sensor (option)
CO2 sensor (option)
NeoFlow sensor (option)



4.4.1 Power-on test

Precondition: The unit is connected to the compressed gas and mains power supply.

Switch on the device.

The unit completes its self-test. At the end of the self-test all LEDs are lit for approx. 2 seconds. The information on the display must not be corrupted by faulty pixels. The final brightness of the display is attained after a few minutes.

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4.4.2 Checking as per internal unit checklist

Precondition: The unit is connected to the compressed gas and mains power supply.

Switch on the device.

If the "CO2" option is available, wait another 3 minutes.

Set unit to "Standby" mode.

Press "Check" softkey on display.

Press "Device Check" softkey on display.
The unit shows the "system", "functional" and "sensor" components on the display.

Press "Check" softkey, shown above menu page.

Follow the relevant dialog highlighted in blue.
Tap the "Yes" or "No" button on the display to confirm or respond to the unit's prompts.

At the end of the unit check the display shows the check sheet, summarising the results of the individual checks. A tick signifies the result is correct. An "F" signifies an incorrect result. Two dashes "- -" signify a check has not been carried out.)
[OK]

Press "Leak test" softkey.

Press the "Check" softkey shown above the menu page and follow the unit's prompts.

☑ **4.5 Testing of safety-related valves** **[_____OK]**

The emergency air valve (Y3.1), the non-return valve (D3.1), the 10 mbar non-return valve (D3.2) and the 100 mbar safety valve (D3.3) are tested.

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☑ **4.5.1** **Emergency air valve Y3.1/non-return valve D3.1** **[_____mbar]**

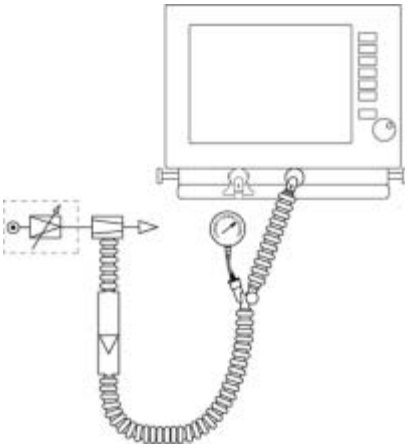
INFO:
The length of the adult ventilation hose between the inspiratory socket and the Y-piece (pressure measurement point) must be 0.9 to 1.2 m.

Precondition: The unit is switched off.

Prepare the following test set-up:

With a test pressure reducer and an injector set a flow of 55 to 60 L/min. The measured value on the reference pressure gauge should be 0 mbar to 6 mbar.

Remove the test set-up.



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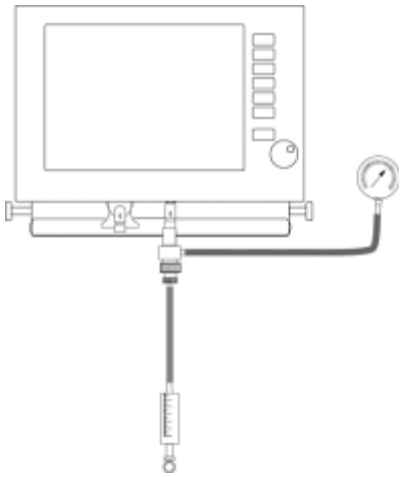
☑ **4.5.2** **Non-return valve D3.2** **[_____mbar]**

Precondition: The unit is connected to the compressed gas supply and switched off.

Prepare the following test set-up:

Use the syringe to feed a volume of 50 mL into the inspiratory socket within 2 seconds to 4 seconds.
The measured value on the reference pressure gauge should be 5 mbar to 10 mbar.

Withdraw the syringe.



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☑ **4.5.3** **Safety valve D3.3** **[_____mbar]**

INFO:
The safety valve automatically relieves the pressure after 3 minutes. To re-activate the safety valve, press the "Standby" button.

INFO:
The alarm "Pressure meas. inop." may be given in this test; it can be ignored. This alarm must disappear again when the test set-up is removed. There may also be a rise in pressure in the test set-up. The reason for this lies in a leak in the mixer, which has not been zeroed after power-on. The mixer is only zeroed when ventilation starts or after 3 minutes at Standby. The test can be performed immediately, however.

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

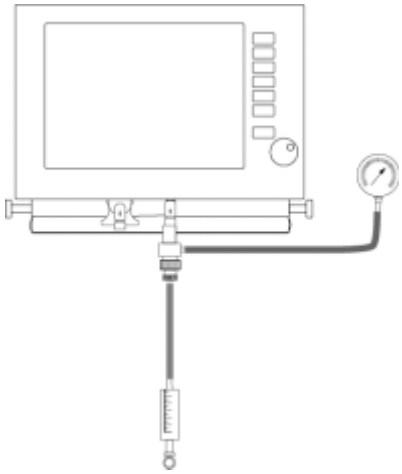
Prepare the following test set-up:

Set EvitaXL to "Standby" mode and confirm.

Use the syringe to feed a volume of 50 mL into the inspiratory socket within 2 seconds to 4 seconds.

The measured value on the reference pressure gauge should be 101 mbar to 110 mbar.

Remove the test set-up.



4.6 IFCO carrier (option)

Precondition: The unit is connected to the compressed gas and mains power supply.

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☑ **4.6.1** **Nurse Call** **[_____OK]**

Switch on the device.
The unit completes its self-test.

Set unit to "Standby" mode.
The "Standby" alarm is activated (Note: Do not clear the "Standby" alarm with the "Alarm Reset" softkey!).
[OK]

Perform a resistance measurement at the EvitaXL's nurse call connector (Note: The nurse call connector is located on the rear of the unit).
Continuity (0 Ohms) between pin 3 and pin 5.
No continuity (high resistance) between pin 3 and pin 1.
[OK]

Press the "Alarm Reset" button.
No continuity (high resistance) between pin 3 and pin 5.
Continuity (0 Ohms) between pin 3 and pin 1.
[OK]

☑ **4.6.2** **PCB detection** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Set unit to "Standby" mode.

Press "System Setup" button.

Press "Service" softkey on display.

Enter code "4655" using display keypad.

The display lists the installed PCBs in plain text.
[OK]

☑ **4.7** **Ambient pressure sensors** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply.

Set unit to "Standby" mode.

Press "System Setup" button.

Press "Service" softkey on display.

Enter code "4655" using display keypad.

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☑ **4.7.1** **Pambient sensor (CO2 Carrier PCB)** **[_____mbar]**

Call up menu option "Sensors" from the "Electronic" menu.

Read out and write down the "Pambient" value.

4.8 Airway pressure sensors

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Press "System Setup" button.
Press "Service" softkey.
Enter access code "4655".

☑ **4.8.1** **Checking sensor plausibility** **[_____mbar]**

Plausibility check of supply pressure sensors and ambient pressure sensor.

Call up menu option "Sensors" from the "Electronic" menu.

Read out the values of the ambient pressure measurement "Pambient", "Raw", "Pair", and "PO2".

☑ **4.8.1.1** **Pambient** **[_____OK]**

INFO:
If the limits are infringed, one or two of the airway pressure sensors is/are outside the tolerance. As a matter of principle the values must be at ambient pressure. If the deviation exceeds 8% "Execute device check" appears whenever the unit is switched on.

The "Pair" and "PO2" values are ascertained in the unit check and must be within the following limits:

(0.94 * Raw) < Test value for "Pair" < (1.06 * Raw)
(0.94 * Raw) < Test value for "PO2" < (1.06 * Raw)

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☑ **4.8.2** **Airway pressure sensors at ambient pressure** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Call up menu option "Sensors" from the "Pneumatic" menu.

Test set-up: Inspiratory and expiratory sockets are open.

Display of "Pressure sensors" in (mbar):
insp: -1.0 mbar to 1.0 mbar
exp: -1.0 mbar to 1.0 mbar

Display of calibration values "Cal" in (V):
insp: 1.34 V to 2.14 V
exp: 1.34 V to 2.14 V

Display of airway pressure measurement "Paw":
Value (CPU PCB) = -2.0 mbar to 2.0 mbar.

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☑ **4.9** **Airway pressure measurement** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Prepare the following test set-up:

Set unit to "Standby" mode.

Remove flow sensor.

Seal off the outlet of the expiratory valve with a rubber bung.

Feed in a flow of maximum 0.2 L/min with a test pressure regulator and set a stable pressure between 60 mbar and 110 mbar (61 cmH2O to 111 cmH2O) as the test pressure.

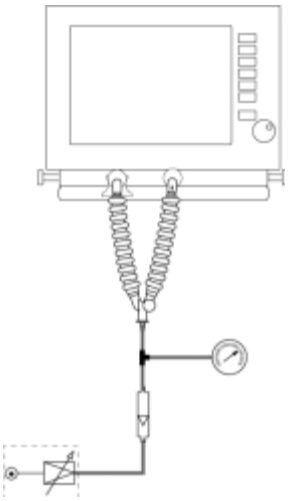
Display of "Pressure sensors" in mbar or cmH2O:

The test pressure attained governs the permissible deviation between the reading on the reference measuring instrument and the display of "insp" and "exp" in service mode:
at 60 to 70 mbar maximum 2.0 mbar for each,
at 70 to 90 mbar maximum 2.5 mbar for each or
at 90 to 110 mbar maximum 3.0 mbar for each.

Display of airway pressure measurement "Paw":
Maximum variance between the values of Paw insp and CPU PCB: 3 mbar.

Checking ”calibration valves” of airway pressure sensors:
Read off and note down the Cal(V) values for the inspiratory and expiratory pressure sensor from the display. After 3 minutes the values may deviate by a maximum of 40 mV from the previously measured values.

Remove all test set-ups. When removing the rubber bung make sure the non-return valve in the expiratory valve is in the correct fitting position.



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☑ **4.10** **Supply pressure sensors** **[_____OK]**

Precondition: If the exact pressure of the compressed gas supply is known (must be between 3.0 bar and 6.0 bar), the compressed gas can be connected directly to the unit.
If the pressure is not known, construct the following test set-up:

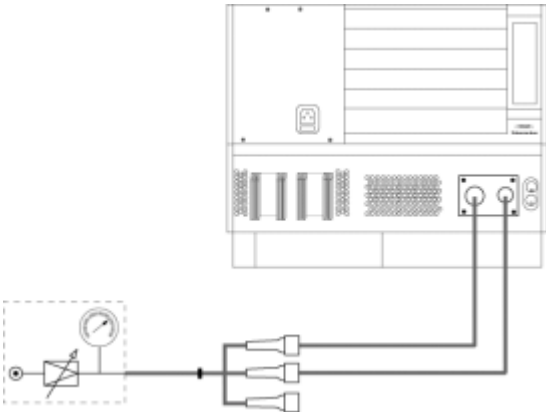
Connect the unit to the mains power supply and switch on.
The unit completes its self-test.

Press "System Setup" button.

Press "Service" softkey.

Enter access code "4655".

From the "Pneumatic" menu select the "Valves" option and read off the values.
Display of supply pressure in Service mode:
PO2 = Pambient + supplied pressure O2 +/-0.2 bar.
PAIR = Pambient + supplied pressure AIR +/-0.2 bar.



4.11 **O2 sensor**

☑ **4.11.1** **O2 sensor** **[_____V]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Set unit to "Standby" mode.

Press "System Setup" button.

Press "Service" softkey on display.

Enter code "4655" using display keypad.

From the "Pneumatic" menu select the "Sensors" option and read off the calibration voltage Cal [V] of the O2 sensor.
The calibration voltage displayed should be 1.3 V.

INFO:
If the displayed calibration voltage falls below 1.3 V it is advisable to replace the O2 sensor, because the minimum voltage of 1.257 V is reached within a short space of time.

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4.12 Ventilation mode IPPV (adult mode)

INFO:
If only the "BIPAP ventilation mode (adult)" test is to be performed, make a note of the user configuration settings, such as the patient range, and re-enter them into the unit at the end of the test.

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Connect adult tubing system without humidifier.
If the adult or pediatric mode was not configured by the user, continue with step "Setting patient range".
If the adult mode is already set, continue with step "Setting ventilation mode".

Setting patient range:
Press "System Setup" button.

Press "Therapy" softkey.

Press "Patient range" softkey.

Enter code "3032".

Press "Triangle" softkey.

Use the control knob to select the adult or pediatric patient range.

Press the control knob.

Press the "New patient" softkey and push the knob.

Press the "Adult" softkey and push the control knob.

Setting ventilation mode:
Press "Ventilator Setting" button.

Press the "IPPV" softkey and push the control knob.

Press the "Additional setting" softkey.

Switch off flow trigger.

Switch off autoflow.

Switch off sigh.

Press "Basic setting" softkey.

Set the following softkeys to the specified parameters and confirm each with the control knob.
"O2" to 21 vol.%
"VT" to 500 mL
"Tinsp" to 2 seconds
"f" to 10 1/min
"Flow" to 25 L/min
"Pmax" to maximum
"PEEP" to 5 mbar

Press the "Alarm limits" key.

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Set the "Paw" softkey (upper alarm limit) to maximum.

Set the "Vti" softkey (upper alarm limit) to maximum.

☑ **4.12.1** **Calibrating sensors** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Press the "Start/Standby" key.

Press the "Sensor Parameter" key.

Press "Flow" softkey.

Press "Start" softkey.
The unit calibrates the flow sensor.
[OK]

Press "O2" softkey.

Press "Start" softkey.
The unit calibrates the O2 sensor.
[OK]

Press the "CO2" softkey (option).

Press "Start" softkey.

Follow the instructions on the dark blue highlighted lines of the display.
The CO2 sensor is calibrated.
[OK]

☑ **4.12.2** **Pressure reducer DR1.1 (AIR)** **[_____mbar]**

Connect the pressure gauge, 0 to 5 bar, to the outlet of the drug nebulizer.

Disconnect the device from the "O2" gas supply.

Press "Special functions …" softkey.

Select the drug nebulizer and confirm with the control knob.
During the inspiratory phase the pressure gauge (AIR) displays a pressure of between 1.75 bar and 2.25 bar.

Switch off the drug nebulizer.

Disconnect the tube from the external pressure gauge (for venting).

Reconnect the "O2" gas supply.

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☑ **4.12.3** **Pressure regulator DR1.2 (O2)** **[_____mbar]**

Connect the pressure gauge, 0 to 5 bar, to the outlet of the drug nebulizer.

Disconnect the device from the "AIR" gas supply.

Press "Special functions …" softkey.

Select the drug nebulizer and confirm with the control knob.
During the inspiratory phase the pressure gauge (O2) displays a pressure of between 1.75 bar and 2.25 bar.

Switch off the drug nebulizer.

Reconnect the "AIR" gas supply.

Disconnect the tube from the drug nebuliser.

☑ **4.12.4** **Drug nebulizer flow (AIR mode)** **[_____L/min]**

Connect a flowmeter (measuring range up to approx. 15 L/min) to the outlet of the drug nebulizer.

Disconnect the device from the "O2" gas supply.

Press "Special functions …" softkey.

Select the drug nebulizer and confirm with the control knob.
The flow rate during the inspiratory flow phase is 7.2 L/min to 11 L/min.

Switch off the drug nebulizer.

Reconnect the "O2" gas supply.

Remove the flowmeter.

Close the "Special functions" window on the display.

4.12.5 **O2 measurement/O2 metering**

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☑ **4.12.5.1** **O2 comparative measurement** **[_____OK]**

The specified O2 value compared with the O2 value measured by the unit and the O2 value measured by an external oxygen tester. The value measured by the unit is shown in the "measured values field".

Connect an external oxygen tester, e.g. MiniOx 3000, to the inspiratory branch.

Set the specified O2 on the unit to 21 vol.%.

Read the measured O2 value (FiO2) from the "measured value field" on the unit and compare it with the value measured by the external oxygen analyzer.
After a few seconds the measured value shown on the unit and the value measured by the external oxygen analyzer is 19 vol.% to 23 vol.%.

Set specified O2 value to 30 vol.%.

Read the measured O2 value (FiO2) from the "measured value field" on the unit and compare it with the value measured by the external oxygen analyzer.
After a few seconds the measured value shown on the unit and the value measured by the external oxygen analyzer is 27 vol.% to 33 vol.%.

Set specified O2 value to 60 vol.%.

Read the measured O2 value (FiO2) from the "measured value field" on the unit and compare it with the value measured by the external oxygen analyzer.
After a few seconds the measured value shown on the unit and the value measured by the external oxygen analyzer is 56 vol.% to 64 vol.%.

Set specified O2 value to 100 vol.%.

Read the measured O2 value (FiO2) from the "measured value field" on the unit and compare it with the value measured by the external oxygen analyzer.
After a few seconds the measured value shown on the unit and the value measured by the external oxygen analyzer is 85 vol.% to 95 vol.%.

Remove the external oxygen tester from the inspiratory branch.

☑ **4.12.5.2** **Oxygenisation for bronchial toilet** **[_____OK]**

Press "Special functions" softkey.

Press "O2 suction" softkey.

Press the control knob.
The oxygen concentration (FiO2) in the measured value field is 97 vol.% to 100 vol.% (Note: The oxygen concentration increases slowly).

Press the "O2 suction" softkey to disable "O2 suction".

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☑ **4.12.6 Flow sensor switch** **[_____OK]**

Disable CO2 monitoring, if installed.

Move the flow sensor slowly to the left.
Starting from the far right, after a distance of 1.5 mm to 4.0 mm a visual "Flowsensor?!!!" alarm is displayed along with the instruction "Insert flow sensor correctly" and an audible alarm.

Push the flow sensor back to the right.

Press "Alarm Reset" softkey.

Press the control knob.

4.12.7 Volume metering/flow measurement in adult mode

The tests are carried out with the basic settings as described under 4.12. Only the specified O2 value is changed in the test.

If the ambient pressure is equal to or greater than 965 mbar, perform the 4.12.7.1 test.

If the ambient pressure is less than 965 mbar, perform the 4.12.7.2 test.

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4.12.7.1 Measurement at high ambient pressure

INFO:
A high ambient pressure is defined as equal to or greater than 965 mbar.

Press "System Setup" button.

Press "Therapy" softkey.

Press the "Modes & setting" softkey.

Enter code "3032".

Press the "Additional setting…" softkey.

Set the "Leakage compensation" menu option to "Off".

Press "System Setup" button.

Press "Therapy" softkey.

Press the "Modes setting" softkey.

Enter the following codes:
3999 3958 = BTPS conversion off
7299 7235 0000 = Set hose compliance correction to 0.
The specified VT value (VTi) is compared against the now humidity-corrected VTe measurement. Perform a flow calibration prior to each measurement.
All settings remain active until the unit is switched off.

Carry out a flow calibration.

Set O2 parameter to 21 vol.%.

Press the "Ventilator Settings" button.

Press the "Data" softkey.

Press the "Values" softkey.
The measured value VTe is 450 mL to 550 mL.

Carry out a flow calibration.

Set O2 parameter to 100 vol.%.

Press the "Ventilator Settings" button.

Press the "Data" softkey.

Press the "Values" softkey.
The measured value VTe is 450 mL to 550 mL (Note: The oxygen concentration increases slowly).
[OK]

INFO:
Up to the 4.15 test item do not switch off the unit! Continue with the 4.13 test item.

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4.12.7.2 Measurement at low ambient pressure

INFO:
A low ambient pressure is defined as less than 965 mbar.

INFO:
Up to the 4.15 test item do not switch off the unit!

Press "System Setup" button.

Press "Service" softkey.

Enter the following codes:
3999 3948 = Leakage compensation off
7299 7235 0000 = Set hose compliance correction to 0.
The VTe readout must be corrected on all units by the humidity error according to the following formula:

In DrägerService Mode from the "Pneumatic" menu select the "Sensors" option and read off the two factors.
The specified VT value (VTi) is compared against the arithmetically humidity-corrected VTe measurement. Perform a flow calibration prior to each measurement.

Set value O2	Measured value Vte
21 vol.%	450 mL to 550 mL
100 vol.%	450 mL to 550 mL

[OK]

If none of the following tests is to be performed re-enter the user configuration settings, such as the patient range, into the unit.

$$V_{Te} = \frac{V_{Te\ display\ value}}{(\text{Factor NTPS} \rightarrow \text{BTPS}) \times (\text{Factor BTPS} \rightarrow \text{NTPD})}$$

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☑ **4.13** **BIPAP ventilation mode (adults)** **[_____OK]**

INFO:
If only the "BIPAP ventilation mode (adult)" test is to be performed, make a note of the user configuration settings, such as the patient range, and re-enter them into the unit at the end of the test.

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Connect a pressure gauge (measuring range up to 120 mbar) between the Y-piece and the test lung, e.g. with a tapered socket (8400904).
If the adult or pediatric mode was not configured by the user, continue with step 2.
If adult mode is already set, continue with step 11.

Press "System Setup" button.

Press "Therapy" softkey.

Press "Patient range" softkey.

Enter code "3032".

Press "Triangle" softkey.

Use the control knob to select the adult or pediatric patient range.

Press the control knob.

Press the "New patient" softkey and push the knob.

Press the "Adult" softkey and push the control knob.

Press "Ventilator Settings" button.

Press the "BIPAP" softkey and push the control knob.

Set the following softkeys to the specified parameters and confirm each with the control knob.
"O2" to 21 vol.%
"Tinsp" to 2 seconds
"f" to 10 1/min
"Ramp" to 0.2 seconds
"Pinsp" to 25 mbar
"PEEP" to 5 mbar
"P ASB" to 0 mbar

Press the "Alarm limits" key.

Set the "Paw" softkey (upper alarm limit) to maximum and push the control knob.

Set the "Vti" softkey (upper alarm limit) to maximum and push the control knob.

Press "System Setup" button.

Press "Therapy" softkey.

Press the "Modes & setting" softkey.

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Enter code "3032".

Press the "Additional setting…" softkey.

Set the "Tube compensation" (option) menu option to "Off".

Close the "System Setup" window.

4.13.1 Pressure measurement and pressure control plausibility test

Press the "Data" softkey.

Press the "Table 1" softkey.
The unit displays the parameter Ppeak at 23 mbar to 27 mbar and the parameter PEEP at 4 mbar to 6 mbar.
The values on the comparative pressure gauge during the inspiratory phase are 23 to 27 mbar and during the expiratory phase 4 mbar to 6 mbar.

Set parameter "PEEP" to 1 mbar.

Press the "Data" softkey.

Press the "Table 1" softkey.
The parameter "PEEP" is displayed on the unit as 0 mbar to 2 mbar.
During the expiratory phase the reference pressure gauge displays a pressure of 0 mbar to 2 mbar.
[OK]

Set "Pinsp" parameter to 50 mbar.

Press the "Data" softkey.

Press the "Table 1" softkey.
The parameter "Pinsp" is displayed on the unit as 47 mbar to 53 mbar.
During the inspiratory phase the reference pressure gauge displays a pressure of 47 mbar to 53 mbar.
[OK]

Set "Pinsp" parameter to 25 mbar.

Remove the tapered socket and the pressure gauge.

If none of the following tests is to be performed re-enter the user configuration settings, such as the patient range, into the unit.

☑ 4.14 Temperature measurement (option) [_____OK]

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

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4.14.1 Test with the ”AWT 01” sensor simulator

Unplug temperatur sensor connector from unit.

Connect the "AWT 01" sensor simulator connector to the unit.

Switch the "AWT 01" sensor simulator to "Test".

Switch the "AWT 01" sensor simulator to "34°C".

Read off the temperature from the "Measured values" window on the display.
The measured value shown in the "Measured values" window on the display is 33 °C to 35 °C.
[OK]

Unplug the "AWT 01" sensor simulator connector from the socket on the unit.

Plug the temperature sensor connector back into the relevant socket on the unit.

4.14.2 Temperature sensor (room temperature measurement)

Perform a comparative temperature measurement at room temperature.

Read off the temperature measurement from the "Measured values" field.
The permissible deviation between the value displayed on the display and the value indicated on the reference thermometer is 2 °C.
[OK]

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☑ **4.15** **Volume metering/flow measurement in pediatric mode** **[_____OK]**

INFO:
Make a note of the user configuration settings, such as the patient range, and re-enter them into the unit at the end of the test.

INFO:
In units with NeoFlow measurement (option) switch off the neonate flow measurement under "Alarms" -> "Monitoring".

INFO:
This test requires compliance of the adult tubing system and the "K" (child) bellows.

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Enter "New patient".

Select only "Pediatric" and confirm.

Disconnect the "Neoflow" flow sensor (option).

Set EvitaXL to "Standby" mode and press the control knob.

Connect the adult tubing system to the bellows "K".
If pediatric mode is not set on the unit, continue with step 4.
If pediatric mode is already set, continue with step 11.

Press "System Setup" button.

Press "Therapy" softkey.

Press "Patient range" softkey.

Enter code "3032".

Press "Triangle" softkey.

Use the control knob to select the pediatric patient group.

Press the control knob.

Press "Ventilator Setting" button.

Press the "IPPV" softkey and push the control knob.

Press the "Additional setting" softkey.

Switch off flow trigger.

Switch off autoflow.

Switch off sigh.

Press "Basic setting" softkey.

Set the following softkeys to the specified parameters and confirm each with the control knob.
"O2" to 21 vol.%
"VT" to 50 mL
"Tinsp" to 1 second

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"f" to 30 1/min
"Flow" to 6 L/min

Press "Ventilator Settings" button.

Set the "Pmax" parameter (upper alarm limit) to maximum and push the control knob.

Set parameter "PEEP" to 0 mbar and push the control knob.

Start the ventilation by pressing the "Standby" key.
At an ambient pressure greater than or equal to 965 mbar perform the 4.15.1 test.
At an ambient pressure less than 965 mbar perform the 4.15.2 test.

4.15.1 Measurement at high ambient pressure

INFO:
A high ambient pressure is defined as equal to or greater than 965 mbar.

INFO:
The unit has not been switched off since test step 4.12.7.1, otherwise re-enter the service numbers indicated there.

The specified VT value (VTi) is compared against the measured VTe value. Perform a flow calibration prior to each measurement.

Carry out a flow calibration.

Set O2 parameter to 21 Vol%.

Press the "Ventilator Settings" button.

Press the "Data" softkey.

Press the "Values" softkey.
The measured value VTe is 40 mL to 60 mL.

Carry out a flow calibration.

Set O2 parameter to 100 vol.%.

Press the "Ventilator Settings" button.

Press the "Data" softkey.

Press the "Values" softkey.
The measured value VTe is 40 mL to 60 mL (Note: The oxygen concentration increases slowly).
[OK]

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4.15.2 Measurement at low ambient pressure

INFO:
A low ambient pressure is defined as less than 965 mbar.

INFO:
The unit has not been switched off since test step 4.12.7.1, otherwise re-enter the service numbers indicated there.

In the following equation, correct the displayed value "VTe" by the humidity error:

Read out the two factors in service mode under "Pneumatic" -> "Sensors".
The specified VT value (VTi) is compared against the arithmetically humidity-corrected VTe measurement. Perform a flow calibration prior to each measurement.

Set value O2	Measured value "Vte" corrected for humidity
21 vol.%	40 mL to 60 mL
100 vol.%	40 mL to 60 mL
[OK]	

Remove the bellows ”K”.

Connect adult tubing system with breathing bag.

Use the standby key to switch to adult mode.

If none of the following tests is to be performed re-enter the user configuration settings, such as the patient range, into the unit.

$$V_{Te} = \frac{V_{Te\ display\ value}}{(\text{Factor NTPS} \rightarrow \text{BTPS}) \times (\text{Factor BTPS} \rightarrow \text{NTPD})}$$

☑ **4.16 Keypad test** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Press the assigned buttons on the control panel one after the other.

The display shows the relevant function of the button pressed. If a button includes an LED, it lights up when the button is pressed.

☑ **4.17 External rechargeable batteries (option)** **[_____OK]**

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4.17.1 Charging circuit

WARNING:
The maximum testing time is 1 minute!

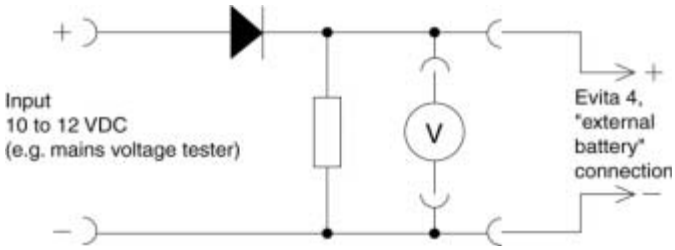
Supply the switched-on unit with mains voltage.

Prepare the following test set-up:

Set voltage on voltmeter in a range between 10 V and 12 V.

With the unit switched on, connect charge tester (7910385) to connection for external battery.

The test set-up simulates a flat battery. The DC power pack of the unit then attempts to charge the rechargeable battery (gel battery 13.8 V or 27.6 V with automatic recognition).
Voltage at voltmeter is pulsed to 20 V or continuously switched.
[OK]



4.17.1.1 Function with external rechargeable batteries

Only perform the test if external rechargeable batteries are fitted in the unit trolley.

Connect the cable connector of the external rechargeable batteries to the power supply unit.

Interrupt mains power supply to the incubator.

The unit remains operative without interruption. The power supply from the external rechargeable batteries is indicated on the display.
[OK]

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☑ **4.18** **CO2 measurement (option)** **[_____OK]**

INFO:
The calibration data are stored in the CO2 sensor, not in the unit!

INFO:
Different test and calibration gases can be used, though the ideal test gas is CO2 in nitrogen.

INFO:
The temperature of the Minican and test set-up must be between 20°C and 30°C for testing and calibration purposes.

INFO:
The value stated on the test filter applies to the given CO2 sensor and not to other sensors! The labelling on the test filter can be changed after calibration with test gas.

Precondition: The unit is connected to the compressed gas and mains power supply and switched on. The internal unit check has been carried out.

Connect the tubing system without a humidifier to the unit.

Set "IPPV" mode.

Start the unit.

If the "CO2" function is not active, press the "Sensor Parameter" button.

Press "CO2" softkey.

Press the "On" softkey and push the control knob.
The lamp in the CO2 sensor lights.

Press the "Sensor Check" softkey.

Slot the CO2 sensor onto the test filter.

Press the "Filter test" softkey.
The value for "FCO2" is indicated on the display. The value matches the figure on the test filter with a tolerance of +/- 0.3Vol.%.
[OK]

Fit the CO2 sensor into the park bracket.

Prepare the following test set-up.

Slot the CO2 sensor onto the adult cuvette.

Test gas Minican 5% CO2, remainder nitrogen (6850435)
Preferentially: Test gas Minican
or with greater test and calibration tolerances:
Test gas Minican 5% CO2, 30% O2, remainder N2O (8290271)
Also possible: Test gas with known CO2 concentration
Test gas with known CO2 concentration between 4.5 vol.% and 5.5 vol.% and known carrier gas comprising nitrogen, oxygen and/or N2O.
The accuracy required for CO2 is 2 % relative.

Read off test gas concentration from test gas cylinder.

Use the "Test gas calibration" softkeys and the control knob to set the

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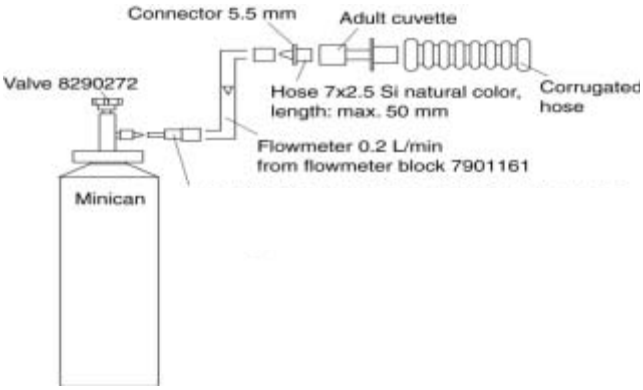
appropriate concentration and confirm.
If the test gas consists only of CO2 and N2, set the O2 and N2O concentration to zero.

Open the test gas cylinder.

Set a flow of 0.15 L/min to 0.25 L/min, reading from the "Air" scale.

Press the "Gas test" softkey.
For CO2 in N2O/O2 as test gas:
The CO2 test value is +/-0.25 vol.% of the CO2 content in the test gas.
[OK]

Switch off the "CO2" measurement function if it was switched off prior to testing.



☑ **4.19** **Patient section heater with fan** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

After about half an hour in operation the temperature of the expiratory valve is markedly higher than the ambient temperature. The force of the fan fitted to the right of the expiratory valve holds a thin piece of paper of about 2 x 2 cm in place at the inlet filter (Note: The inlet filter is located to the right of the expiratory valve and is visible from below).

Clean the fan grille and the fan as necessary.

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☑ **4.20** **Touchscreen** **[_____OK]**

Precondition: The unit is connected to the compressed gas and mains power supply and switched on.

Connect a service PC to the unit.

Launch the unit's service software.

Switch on the device.

Call up menu option "Touch Screen" from the "Front panel" menu.

Select the "Test columns" menu option.

Run your finger slowly, and applying even pressure, across the touchscreen from left to right.
The display is highlighted in black at your finger's position.

Select the "Test lines" menu option.

Run your finger slowly, and applying even pressure, across the touchscreen from top to bottom.
The display is highlighted in black at your finger's position.

☑ **4.21** **Interfaces** **[_____OK]**

Precondition: Connect the RS232 adapter (7901888) and the RS232 extension cable (7901808) to the unit (COM1). Connect the other end of the RS232 extension cable to the service PC. The unit is connected to the compressed gas and mains power supply and switched on.

Start the "Meditest" service program (software version 7.n or higher).

Launch service mode from the "EvitaXL unit selection" menu.

Then switch the unit off briefly and back on again.

☑ **4.21.1** **COM1** **[_____OK]**

Following the self-test the unit indicates "Service Mode" on its display.

☑ **4.21.2** **COM2 (option)** **[_____OK]**

In the service program, call up menu option "RS232 Test" from the "Communication" menu.

Plug the RS232 shorting plug (790885) into the "COM2" socket of the unit.

Press the on-screen "Send" button.
Response on service PC for COM2: "OK"

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☑ **4.21.3** **COM3 (option)** **[_____OK]**

In the service program, call up menu option "RS232 Test" from the "Communication" menu.

Plug the RS232 shorting plug (790885) into the "COM3" socket of the unit.

Press the on-screen "Send" button.
Response on service PC for COM3: "OK"

☑ **4.21.4** **Analog outputs (option)** **[_____OK]**

Connect the analog port test cable (7910456) to the unit's analog output.

4.21.4.1 **Analog output**

Connect a voltmeter to the respective sockets of the analog output test cable.

In the service program, call up menu option "Analog output" from the "Communication" menu and start the test.

Enter the respective specified values and test the output voltages.

Setpoint	Test value
0000 mV	0 mV to 5 mV
2050 mV	2040 mV to 2060 mV
4095 mV	4075 mV to 4115 mV

[OK]

4.21.5 **ILV port**

Connect the ILV port test connector (7910455) to the ILV port on the unit.

In the service program, call up menu option "ILV" from the "Electronics" menu and start the test.

Response on PC: ”O.K”.
[OK]

☑ **4.22** **Unit prior to handover** **[_____OK]**

WARNING:
If the unit includes the external rechargeable battery option, check that the red cable connector is connected to the rear of the power supply unit.

Charge the internal and external batteries. Otherwise it will not be possible to run the unit on the fitted batteries in the event of a mains power failure!

☑ **4.23** **Unit handover** **[_____OK]**

Place fully functional unit at the user's/owner's disposal.

☑ **4.23.0** **Signature** **[_____txt]**

☑ **4.23.0** **Name** **[_____txt]**

☑ **4.23.0** **Date** **[_____dat]**

Annex to the PMS procedure

1 Test equipment

1.1 Test equipment subject to calibration

Designation	Order no.	Remark
Torque spanner	7900909	
Pressure gauge, electronic	7910724	for 250 mbar, 2 bar, 20 bar
Flowmeter	7900718	10 L/min to 120 L/min
Flowmeter	7900718	0.01 L/min to 14 L/min
Multimeter	7901021	Multimeter with 4 3/4 digits
O2 test pressure regulator	7901482	The test pressure reducer is normally shipped with a cylinder connection for G3/3" (R3/4"). Other cylinder connections are possible. Please specify when ordering.
Secutest	7910596	
Stopwatch	7910299	
Temperature sensor dummy	7900405	

1.2 Test equipment not subject to mandatory calibration

Designation	Order no.	Characteristics/Info
5.5 mm connector from catheter connector set	8403684	
Breathing bag with 7 mm catheter connector, set	8403201	
Bellows	8403208	
DC voltage source (10 V to 12 V)	7910426	Only included in old VDE tester case

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Designation	Order no.	Characteristics/Info
Corrugated hose	8402041	
Gas distributor	7901495	For test pressure regulator 7901482 with German central supply connections for AIR, O2 and N2O.
Injector	7900930	For test pressure regulator 7901482
Tapered socket	8400904	
Charge tester (Evita), complete	7910385	
Leakage current measuring lead, 9-pin, at ILV port	7910393	Alternatively: Temperature module measuring lead 7910364
Measuring lead, red, 1 m	7901022	Required quantity 2
Measuring lead, black, 1 m	7901023	Required quantity 2
Minican 5% CO2, 65% N2O, 30% O2	8290271	
Nellcor test simulator, set	7901069	For testing of SpO2 measurement (option)
Test gas Preferentially: Minican 5 % CO2, rest nitrogen (the most suitable gas mixture) or with greater test and calibration tolerances:	6850435	Different test and calibration gases can be used, though the ideal test gas is CO2 in nitrogen.
Test cable, analog port	7910456	
Test connector, ILV port	7910455	
Hose 2 x 1 Si natural	1180614	Length as specified
Hose 4 x 1.5 Si natural	1190520	Length as specified
Hose 6 x 2.5 Si natural	1197851	Length as specified

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Designation	Order no.	Characteristics/Info
Hose 7 x 2.5 Si natural	1198343	Length as specified
Tubing systems		As specified in Instructions for Use
Special open-ended wrench, width 41	7910462	For single-column trolley
Syringe	7901541	
Test cable, 9-pin	7901888	
Test cable, RS232 extension	7901808	
Test connector, COM 2-6 (RS 232 shorting plug)	7901885	
Thermometer	2M11111	
Tapered socket	8400904	
Valve	7910488	For Minican
Y-piece (5x)	2M12754	
CS connecting hoses for O2 and AIR		As specified in Instructions for Use.

2 Technical Information

2.1 Designations

International designation	US designation
IPPV	CMV
BIPAP	PCV+
ASB	Pressure Support

2.2 Units conversion table

1 mbar	=	1.02 cm H2O
1 cm H2O	=	0.98 mbar
1 bar	=	14.505 psi
1 inch	=	25.4 mm
1 Nm	=	0.74 lb-ft

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2.3 Hose diagrams

2.3.1 Hose diagram of pneumatic system with Dräger gas connection block

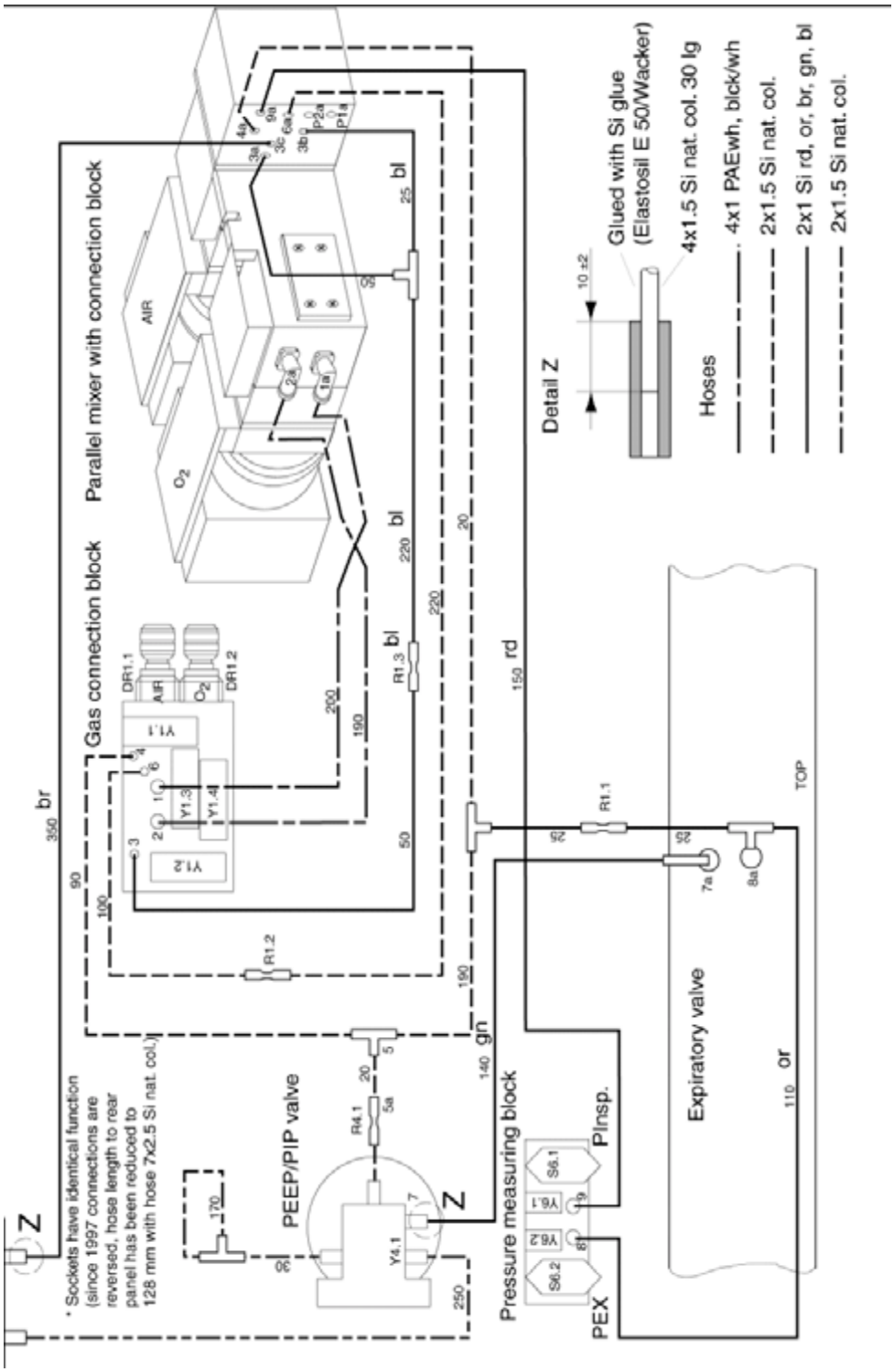

Fig. 1 Hose diagram of pneumatic system with Dräger gas connection block

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2.3.2 Hose diagram of pneumatic system with FAS gas connection block

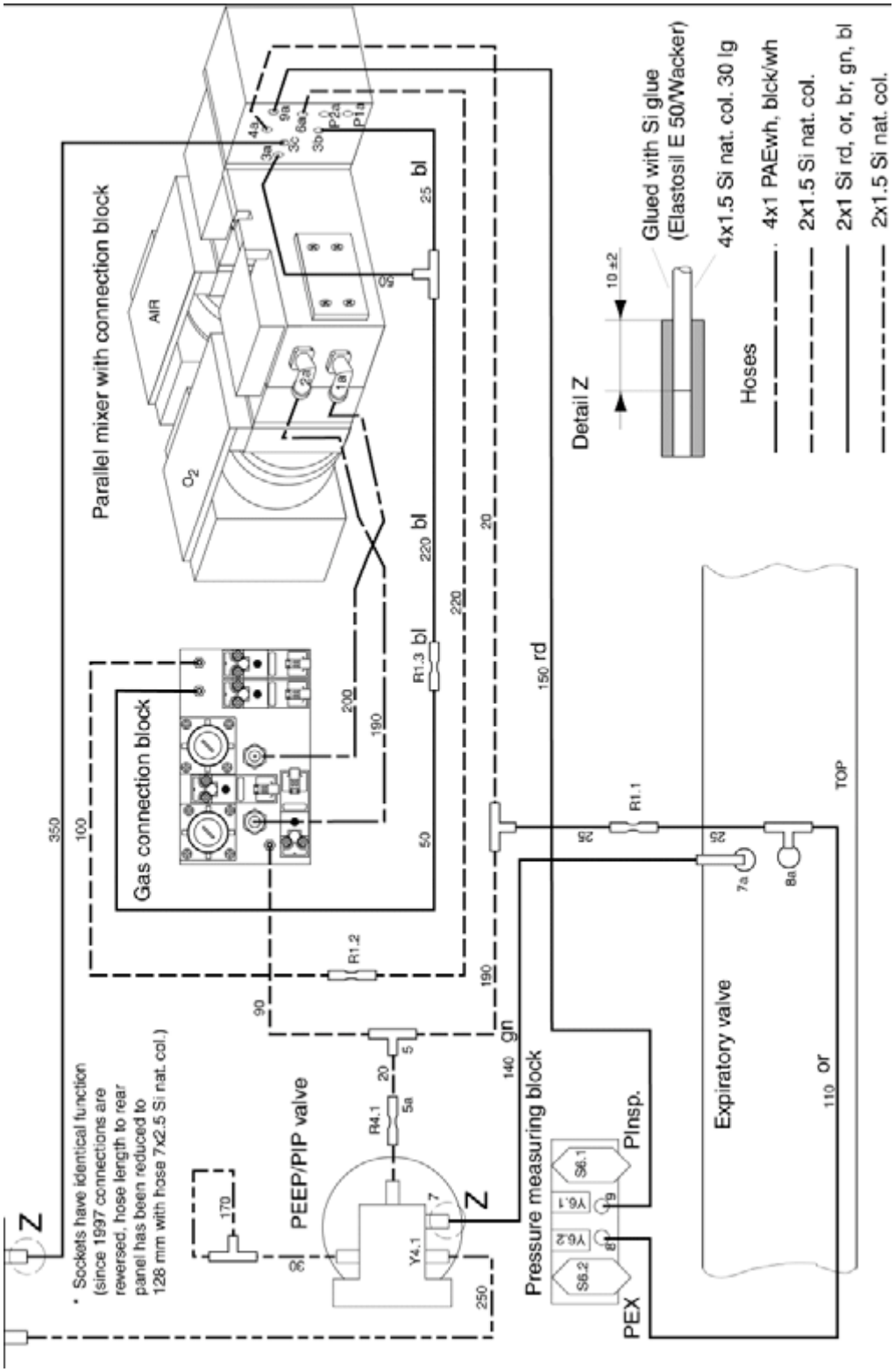

Fig. 2 Hose diagram of pneumatic system with FAS gas connection block

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2.4 Pneumatic diagram

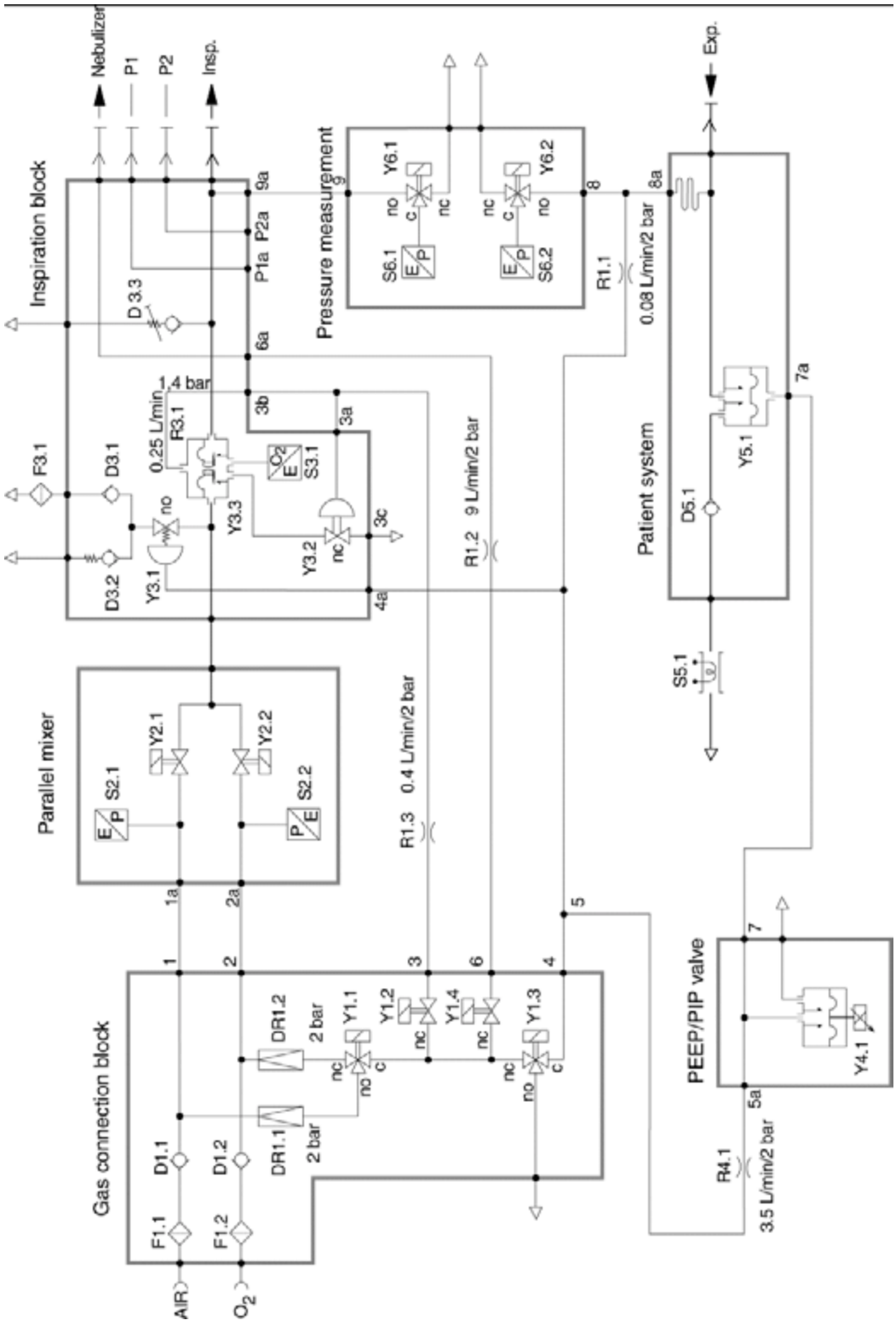

Fig. 3 Pneumatic diagram

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